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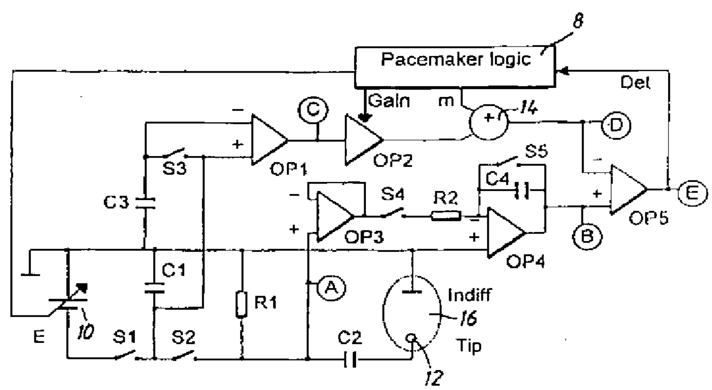
(71) Applicant: **Pacesetter AB**
175 84 Järfälla (SE)

(72) Inventor: **Holmström, Nils**
17557 Järfälla (SE)

(54) Heart stimulator

(57) A heart stimulator comprises a pulse generator devised for producing stimulation pulses of varying amplitudes and varying durations for stimulating the heart of a patient (16), and an evoked response detector. The evoked response detector includes measuring and memory means (C3, S3, OP1, OP2, 14) for measuring the charge Q delivered by a stimulation pulse. The measuring and memory means are adapted for determining and storing as a reference voltage a charged voltage value U_D related to the measured charge. Monitoring means (C2, OP3, S4, R2, OP4, C4, S5) are provided for monitoring the combined polarization and possible evoked response signal $u_A(t)$ picked up from the patient's heart after the delivery of a stimulation pulse and deriving a corresponding monitoring voltage value U_B. Comparison means (OP5) are provided for comparing the monitoring voltage value with said charged voltage value for determining, from the result of the comparison, the presence or absence of an evoked response.

Fig. 4



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Description

Technical Field

[0001] The present invention relates to an evoked response detector for a heart stimulator for determining evoked response in the presence of polarization, said heart stimulator comprising a pulse generator devised for producing stimulation pulses of varying amplitudes and varying durations for stimulating the heart of a patient, said evoked response detector comprising measuring and memory means for measuring the charge delivered by a stimulation pulse. The invention also relates to such a heart stimulator.

Background Art

[0002] There is a need to make unipolar pacemakers, both for ventricular and atrial stimulation of the heart of a patient, that have a so-called AUTOCAPTURE™ pacing system function. The AUTOCAPTURE™ function is used to maintain the energy of the stimulation pulse at a level just above the level which is needed to effectuate capture, cf. e.g. US-A-5,458,623. In this connection it is difficult to detect evoked response in a safe and reliable manner, since the evoked response potential is small in amplitude compared to the residual polarization after the stimulation pulse and this polarization is varying when the stimulation energy is varied for threshold search. The polarization is also varying with variations of the impedance.

[0003] Several attempts have been made to solve the polarization problems in connection with evoked response detection. Thus US-A-5,417,718 discloses a system for maintaining capture, wherein an electrical post-stimulus signal of the heart following delivery of a stimulation pulse is compared to a polarization template, determined during a capture verification test. A prescribed difference between the polarization template and the post-stimulus signal then indicates capture. Otherwise loss of capture is presumed and the stimulation energy is increased a predetermined amount to obtain capture.

[0004] One technique of reducing the effects of polarization is to remove the polarization charge by supplying after the delivery of the stimulation pulse one or more suitable pulses of opposite polarity , see e.g. US-A-4,811,738.

[0005] US-A-5,431,693 describes a method of verifying capture of the heart by a pacemaker. Observing that the non-capture potential is exponential in form and the evoked capture potential, while generally exponential in form, has one or more small-amplitude perturbations superimposed on the exponential wave form. These perturbations are enhanced for ease of detection by processing the wave forms signal by differentiation to form the second derivative of the evoked response signal for analysis for the evoked response detection.

[0006] Unipolar detection of evoked response signals is, however, not possible by this technique. Abrupt slope changes or superimposed small-amplitude perturbations are leveled out when the measurements are made over a longer distance from the electrode to the stimulator casing. In Swedish patent application No. 9703600-8 (US-09/161.665 and EP-98116180.5) an evoked response detector is described which has a function based on the fact that the evoked response signal amplitude does not vary significantly with the amplitude of the stimulation pulse (provided that the stimulation amplitude is above the capture threshold), whereas the electrode polarization is approximately linearly dependent on the stimulation pulse amplitude for a constant pulse duration within a certain stimulation pulse amplitude range for distinguishing the evoked response signal from the polarization signal.

[0007] Experiments have now shown that polarization of stimulation electrodes is proportional to the charge of the delivered stimulation pulse. The purpose of the present invention is to provide an improved detector for determining evoked response based on this discovery, which makes detection of evoked response possible with the aid of unipolar as well as bipolar stimulation electrodes, implanted in the ventricle or in the atrium of the heart of a patient. The purpose of the invention is also to provide a heart stimulator equipped with such a detector.

Disclosure of the Invention

[0008] This purpose is obtained with an evoked response detector according to the introductory portion of the description having the characterizing features of claim 1 and a heart stimulator according to claim 11.

[0009] Thus, in the detector according to the invention the charge of a stimulation pulse is measured and a corresponding charge voltage value is determined as a reference value, and the polarization and possible evoked response signal is monitored after delivery of the stimulation pulse and compared to this reference value for determining the presence or absence of an evoked response. Thus, in this way evoked responses can be reliably detected for stimulation pulses of varying output energies e.g. during a threshold search by eliminating the influence of varying polarization on the detected cardiac evoked response. By using the measured delivered charge in this way for compensating for the polarization of the evoked response signal, it is possible to create a fully automatic evoked response detector for all kinds of uni- and bipolar electrodes, for all stimulation pulse amplitudes and every possible pulse duration. The detector is especially useful for stimulation threshold search when pulse duration or pulse amplitude or both these parameters are changed at the same time. Also variations of the lead impedance are compensated for without need to manually adjust the detector settings.

[0010] According to advantageous embodiments of the detector according to the invention said measuring and memory means are adapted to determine the charge voltage value U_D by the relation

$$U_D = k \cdot Q + m$$

where k denotes a variable factor chosen such that U_D is equal to the measured polarization with m = 0, Q the charge of a stimulation pulse, and m an evoked response detection voltage margin. In this way the charged voltage value U_D can be automatically determined by adjusting the factor k by tuning of an amplifier gain.

[0011] According to still another advantageous embodiment of the detector according to the invention the evoked response detection voltage margin m is proportional to the charged voltage value U_D. This is an important feature for maintaining a detection voltage margin m of constant relative magnitude. If the evoked response voltage margin m were equal to a constant value the detection voltage margin m would be relatively higher for low voltage values U_D than for high values.

[0012] According to yet another advantageous embodiment of the detector according to the invention said monitoring means are adapted to determine said monitoring voltage value equal to a value of the combined polarization and possible evoked response signal sampled at a predetermined time after delivery of the stimulation pulse. The sampling operation is then preferably performed at a time when the best evoked response signal is expected. This time can typically be about 2 msec after the beginning of the stimulation pulse.

[0013] According to still another advantageous embodiment of the detector according to the invention said monitoring means are adapted to determine said monitoring voltage value U_B by integrating the voltage signal $u_A(t)$ picked up from the patient's heart over a predetermined time interval after delivery of the stimulation pulse The potential of the stimulation electrode is then integrated over a time interval in which a good reproducible evoked response signal is expected. This is a reliable method for determining evoked response which allows large individual morphology variations in the evoked response signal.

[0014] According to another advantageous embodiment of the detector according to the invention said comparison means are adapted to indicate evoked response if said monitoring voltage value U_B exceeds said charged voltage value U_D. If this condition is not fulfilled loss of capture is indicated.

[0015] According to an advantageous embodiment of the heart stimulator according to the invention the pulse generator is controlled to deliver stimulation pulses of as high amplitudes as possible without the use of voltage doubling means. Since the stimulation charge threshold decreases with decreasing pulse duration, see e.g. Furman, "A Practice of Cardiac Pacing", Second edition, Futura Publishing Company, New York, 1989, pp. 42-49 and the following, the polarization at the stimulation threshold is lower for a shorter pulse width. The battery current drain for stimulation at the threshold is also lower for shorter pulses as long as the stimulation amplitude is below the battery voltage of the stimulator. Therefore it is recommendable to stimulate with the highest voltage possible that does not require voltage doubling means, i.e. 2.8 V in practice, and consequently reduce the pulse width towards the duration threshold. If so, the evoked response sensing will be facilitated and current consumption will be minimal. This is further discussed in connection with tissue stimulation in general in US-A-5,391,191.

[0016] According to still another advantageous embodiment of the heart stimulator according to the invention microprocessor means are provided for storing and analyzing data on detected polarization and evoked response threshold variations. From these data electrode micro-dislocations and other electrode lead disorders can be disclosed.

Brief Description of the Drawings

[0017] To explain the invention more in detail as examples chosen embodiments of the detector according to the invention will now be described with reference to the drawings, on which

[0018] Fig. 1 and fig. 2 show the relation between measured polarization and the charge of stimulation pulses for different pulse widths measured directly after the stimulation pulse and 2 msec after the beginning of stimulation pulse respectively; fig. 3 illustrates an embodiment of the detector according to the invention; fig. 4 shows the electronic circuitry of a realization of a heart stimulator according to the invention; fig. 5 and 6 are timing diagrams illustrating the operation of the stimulator in fig. 4 in two different modes of operation.

Description of Preferred Embodiments

[0019] Figs. 1 and 2 show the results of in vitro measurements of the polarization as a function of the charge of stimulation pulses for pulses of varying widths. The polarization voltage was measured in a physiological saline solution, a so called Ringer-solution, between a tip electrode and an indifferent electrode. Fig. 1 shows the result of measurements performed directly after the termination of the stimulation pulse and fig. 2 shows the result of measurements after 2 msec after the beginning of the stimulation pulse. The width of the stimulation pulse is typically somewhat less than 0.5 msec. In fig. 1 a somewhat lower polarization was measured for wide pulses than for short ones for equal stimulation charge. This depends on the fact that polarization from the beginning of the stimulation pulse has declined for wide pulses. Fig. 2 shows a good linear relationship between

the polarization and the delivered charge of stimulation pulse, independently of the pulse width. This linear relationship between polarization and stimulation charge is used in the detector according to the invention.

[0020] In the detector according to the invention the charge Q delivered by a stimulation pulse is measured and stored on one channel. The resulting polarization together with a possible evoked response after the stimulation pulse $u_A(t)$ is monitored on another channel, se fig. 3. The charge Q is processed to a corresponding voltage value according to the equation

$$U_D = k \cdot Q + m \qquad (1)$$

where k is a variable factor chosen to be equal to the measured polarization with m equal to 0. The charge voltage value U_D is determined in block 2 in fig. 3 and forms a reference value for a subsequent comparison. The factor k has the nature of a gain and the determination or tuning of the factor k can be performed automatically as will be described below. m denotes an evoked response detection margin and is preferably proportional to the amplitude of the voltage U_D, as mentioned above. If m were chosen to be a constant its relative magnitude should be much larger for low amplitudes than for high ones. The detection margin m is chosen low enough for avoiding undersensing, i.e. making the detector too insensitive for the detection of evoked response signals, but high enough to depress noise and polarization variations, i.e. avoid oversensing of the detector. Thus with a detector according to the invention the detection margins for evoked response under- and oversensing can be continuously followed after each stimulation pulse without losing capture.

[0021] A monitoring voltage value U_B can be determined from the combined polarization and evoked response signal $u_A(t)$ in at least two different ways.

[0022] The voltage U_B can be determined by sampling the potential of the stimulation electrode at a specified time t_x after the stimulation, preferably at a time when the best evoked response signal is expected.

[0023] An alternative way of determining the voltage U_B consists in integration of the polarization and possible evoked response signal $u_A(t)$ over a time interval after the stimulation pulse when a good reproducible evoked response signal is expected, e.g. at 2 msec after the beginning of the stimulation pulse, cf. the discussion of fig. 2. This latter way of determining the voltage value U_B is performed in block 4 in fig. 3 and allows large individual evoked response morphology variations and is more reliable than the above mentioned sampling procedure.

[0024] The two voltages U_D and U_B are then compared in a comparator 6, and if $U_B > U_D$ detection of evoked response is indicated, otherwise loss of capture is indicated.

[0025] Fig. 4 shows an example of the electronic circuitry of a heart stimulator according to the invention including an evoked response detector as described above. For the explanation of the operation of the stimulator reference is also made to the timing diagram in fig. 5. The curves Pol and ER following the stimulation pulse in the u_A-time diagram in fig.5 represent the polarization signal and the combined polarization and evoked response signal respectively.

[0026] From the pacemaker logic unit 8 the voltage E of the variable voltage source 10 is adjusted equal to the desired stimulation amplitude in the time interval t_5-t_1 in fig. 5, between the stimulation pulses. In this phase the switches S1 and S3 are closed and the capacitors C1 and C3 are charged to the voltage E.

[0027] At time t_1 the switches S1 and S3 are opened and switch S2 is closed and a stimulation pulse is delivered to the electrode tip 12 implanted in a patient 16.

[0028] The switch S5 is also closed at this time to reset the voltage on the capacitor C4 for the next evoked response detection. During the stimulation phase the capacitor C1 is discharged while the voltage on the capacitor C3 remains unchanged. Amplifier OP1 is an instrumental amplifier with unity gain, and its output voltage U_C will increase during the stimulation pulse proportionally to the delivered charge Q and at the time t_2 the voltage U_C has reached the level Q/C1, see fig. 5. This voltage U_C is gained with a factor G in the amplifier OP2 and a voltage value m is added in the adder 14 to form the voltage

$$U_D = G \cdot Q/C1 + m \qquad (2)$$

[0029] This voltage U_D is constant between the time t_2 and t_5, cf. fig. 5, and constitutes the charged voltage value used as reference for subsequent evoked response detection. The detection margin m is delivered by an AD-converter in the pacemaker logic unit 8.

[0030] Between the times t_3 and t_4 the switch S4 is closed and the sensed polarization and evoked response signal is integrated on the capacitor C4 according to the equation

$$U_B = \frac{1}{R_2 C_4} \int_{t_3}^{t_4} u_A(t)dt \qquad (3)$$

where R_2 denotes an input resistance to amplifier OP4.

[0031] The voltages U_D and U_B are compared in the comparator OP5 and the indication for capture is that $U_B > U_D$ in the time window between t_4 and t_5, see fig. 5.

[0032] By increasing the magnitude of the detection margin m till the comparator OP_5 toggles directly after detection of capture it is possible to test the evoked response amplitude margin m.

[0033] The output signal from the comparator OP5, indicating whether evoked response is detected or not, is supplied to the pacemaker logic unit 8 for controlling the continued operation of the heart stimulator.

[0034] With microprocessor technique data regarding polarization and threshold variations can be stored and analyzed in the heart stimulator according to the invention, i.e. for disclosing electrode micro-dislocations and other lead disorders.

[0035] One preferred way of setting the above mentioned gain G, cf. equation (2), will now be described.

[0036] A stimulation pulse is then delivered in the refractory period of the patient's heart or a pulse below the stimulation threshold is delivered. No evoked response signal is then added to the voltage signal u_A sensed on the node A in fig. 4. Thus the sensed voltage u_A just represents the polarization, see fig. 6. Between the times t_3 and t_4 the polarization from the preceding stimulation pulse is integrated on the capacitor C4. This voltage U_B is held on node B from the time t_4 until the switch S5 is closed again.

[0037] The charge delivered during a stimulation pulse amounts to

$$Q = C1 \cdot \Delta U$$

where ΔU is the voltage on node C, which is constant after time t_2. The amplification factor G of the programmable amplifier OP2 is then adjusted from the pacemaker logic unit 8 so that the amplifier output voltage equals the voltage on node B ($G' \cdot \Delta U = U_B$). This condition is fulfilled when the comparator OP5 toggles and an output pulse u_E is obtained on the output of the comparator OP5, cf. fig. 6. During this calibration procedure the m-value is set equal to zero.

[0038] Since the polarization is proportional to the delivered charge for all pulse widths and amplitudes, the new amplification factor G' can be used for any pulse configuration thereafter to distinguish between capture and loss of capture. To get a defined detection margin m in Volt, U_D is increased with a constant value of m applied from the pacemaker logic unit 8. The new reference voltage on node D is then equal to $G' \cdot U + m$, and if the integrated polarization on node B after a stimulation pulse is higher than the above mentioned reference voltage capture is detected, otherwise the stimulation resulted in a loss of capture.

[0039] An alternative method of determining the gain factor G comprises stimulation with two different output charges Q1 and Q2, both these charges being above the stimulation threshold and both resulting in capture. The gain for both stimulation pulses is then adjusted, with the stimulation margin m set equal to 0, from the pacemaker logic unit 8, such that the comparator QP5 just toggles. Since the polarization signal will be proportional to the charge of the stimulation pulses, whereas the evoked response signal is independent of the charge, it is possible to calculate the gain factor G. Thus the following equations are valid.

$$U_B(Q1) = K^*Q1+ER=G1^*Q1/C1 \qquad (4)$$

$$U_B(Q2) = K^*Q2+ER=G2^*Q2/C1 \qquad (5)$$

From these equations (4) and (5) the quantity K is obtained as

$$K = \frac{G1 \cdot Q1 - G2 \cdot Q2}{C1(Q1 - Q2)} \qquad (6)$$

where G1 and G2 denote the adjusted gains for the two stimulation pulses and ER denotes the evoked response signal. For ER = 0 the following equation is valid

$$U_B(Q) = K^*Q = G^*Q/C1 \qquad (7)$$

[0040] By eliminating the quantity K between the above equations (6) and (7) the following expression is obtained for the desired gain G

$$G = \frac{G1 \cdot Q1 - G2 \cdot Q2}{Q1 - Q2} \qquad (8)$$

[0041] When the desired gain G is known it is just to use the actual setting for the next evoked response measurement.

Claims

1. An evoked response detector for a heart stimulator for determining evoked response in the presence of polarization, said heart stimulator comprising a pulse generator devised for producing stimulation pulses of varying amplitudes and varying durations for stimulating the heart of a patient (16), said evoked response detector comprising measuring and memory means (2; C3, S3, OP1, OP2, 14) for measuring the charge Q delivered by a stimulation pulse, **characterized in** that said measuring and memory means (2; C3, S3, OP1, OP2, 14) are adapted for determining and storing as a reference voltage a charge voltage value U_D related to the measured charge Q, in that monitoring means (4; C2, OP3, S4, R2, OP4, C4, S5) are provided for monitoring the combined polarization and possible evoked response signal $u_A(t)$ picked up from the patient's (16) heart after the delivery of a stimulation pulse and deriving a corresponding monitoring voltage value U_B and in that comparison means (6; OP5) are provided for comparing said monitoring voltage value U_B with said charge voltage value U_D for determining, from the result of the comparison, the presence or absence of an evoked response.

2. The evoked response detector according to claim 1, **characterized in** that said measuring and memory means (2; C3, S3, OP1, OP2, 14) are adapted to

determine the charge voltage value U_D by the relation

$$U_D = k \cdot Q + m$$

where k denotes a variable factor, Q the charge of a stimulation pulse, and m an evoked response detection voltage margin.

3. The evoked response detector according to claim 2, **characterized in** that said factor k is chosen such that the charge voltage value U_D is equal to the measured polarization with the evoked response detection voltage margin m = 0.

4. The evoked response detector according to claims 2 or 3, **characterized in** that the evoked response detection voltage margin m is proportional to the charge voltage value U_D.

5. The evoked response detector according to any of the preceding claims, **characterized in** that said monitoring means are adapted to determine said monitoring voltage value U_B equal to a value of the combined polarization and possible evoked response signal $u_A(t)$ sampled at a predetermined time after delivery of the stimulation pulse.

6. The evoked response detector according to claim 1 through 4, **characterized in** that said monitoring means (4; C2, OP3, S4, R2, OP4, C4, S5) are adapted to determine said monitoring voltage value U_B by integrating the voltage signal $u_A(t)$ picked up from the patient's (16) heart over a predetermined time interval after delivery of the stimulation pulse.

7. The evoked response detector according to any of the preceding claims, **characterized in** that said comparison means (6; OP5) are adapted to indicate evoked response if said monitoring voltage value U_B exceeds said charge voltage value U_D.

8. The evoked response detector according to any of the claims 2 through 7, **characterized in** that in order to determine said factor k an amplifier with an adjustable gain is provided for amplifying the charge voltage value U_D without evoked response detection margin m such that it becomes equal to the monitoring voltage value U_B obtained from the polarization signal resulting from a stimulation pulse delivered in the refractory period of the patient's (16) heart.

9. The evoked response detector according to any of the claims 2 through 7, **characterized in** that in order to determine said factor k an amplifier with an adjustable gain is provided for amplifying the charge voltage value U_D without detection margin m obtained from a stimulation pulse with an energy below the stimulation threshold such that the charge voltage value U_D becomes equal to the monitoring voltage value U_B obtained from said stimulation pulse.

10. The evoked response detector according to any of the claims 2 through 7, **characterized in** that in order to determine said factor k an amplifier with an adjustable gain is provided for amplifying the charge voltage value U_D without detection margin m such that it becomes equal to the monitoring voltage value U_B for two stimulation pulses of different charges Q_1,Q_2 above the evoked response threshold resulting in capture, and in that means are provided for calculating from the charges Q_1,Q_2 and the adjusted gains G_1,G_2 for the two stimulation pulses the gain G intended to be used for setting the charge voltage value U_D for the next evoked response measurement.

11. A heart stimulator, **characterized by** a detector according to any one of the preceding claims.

12. The heart stimulator according to claim 11, **characterized in** that an AD converter of the stimulator logic unit (8) is adapted to deliver the evoked response detection voltage margin (m).

13. The heart stimulator according to claim 11 or 12, **characterized in** that the pulse generator is controlled to deliver stimulation pulses of as high amplitudes as possible without the use of voltage doubling means.

14. The heart stimulator according to any of the claims 11 through 13, **characterized in** that microprocessor means are provided for storing and analyzing data on detected polarization and evoked response threshold variations.

Fig. 1

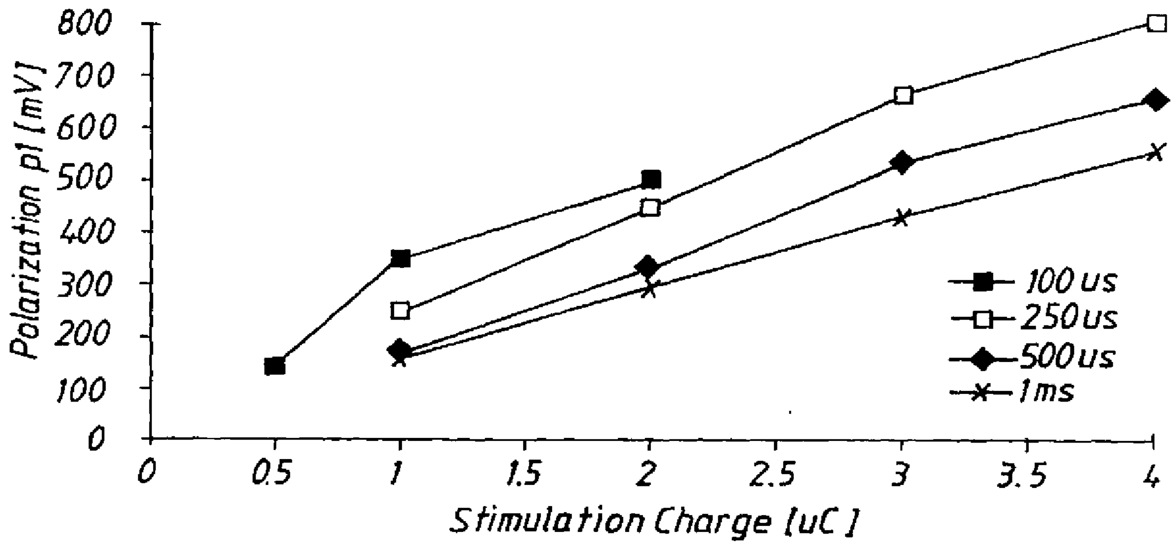
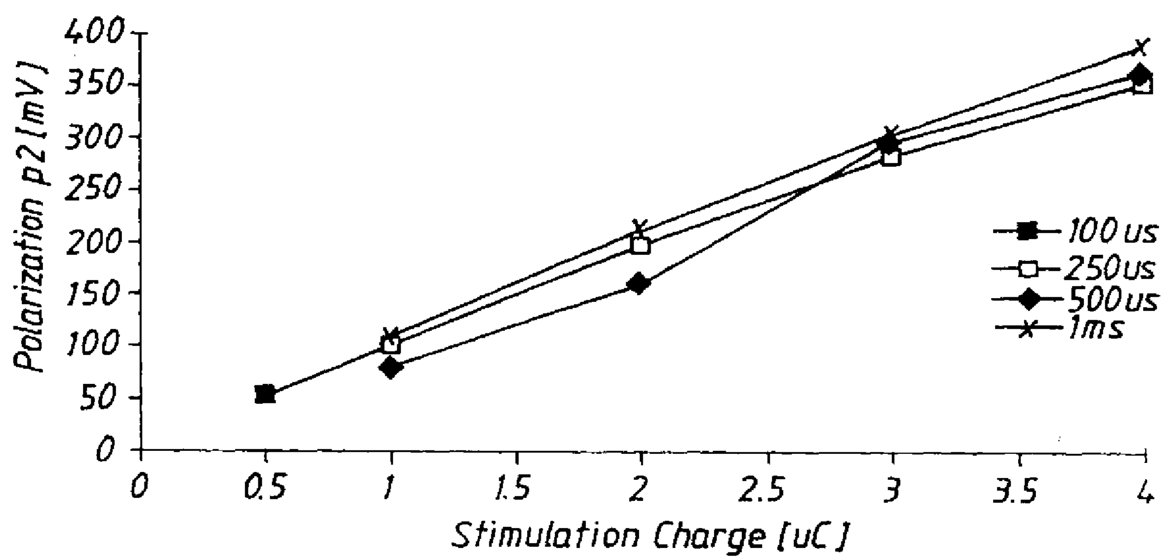

Polarization p1 [mV]
800
700
600
500
400
300
200
100
0
0
0.5
1
1.5
2
2.5
3
3.5
4
Stimulation Charge [uC]
100 us
250 us
500 us
1 ms

Fig. 2


Polarization p2 [mV]
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350
300
250
200
150
100
50
0
0
0.5
1
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2
2.5
3
3.5
4
Stimulation Charge [uC]
100 us
250 us
500 us
1 ms

Fig. 3

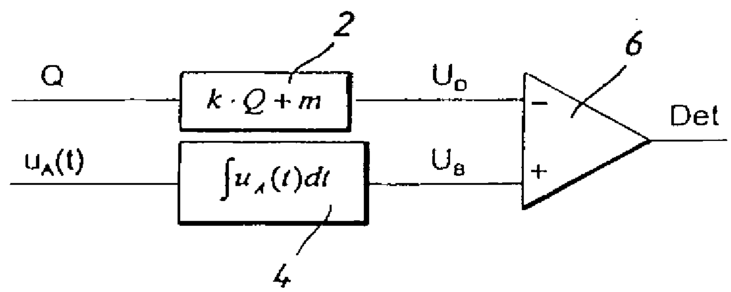

2
6
Q
$k \cdot Q + m$
U_D
Det
$u_A(t)$
$\int u_A(t)dt$
U_B
4

Fig. 4

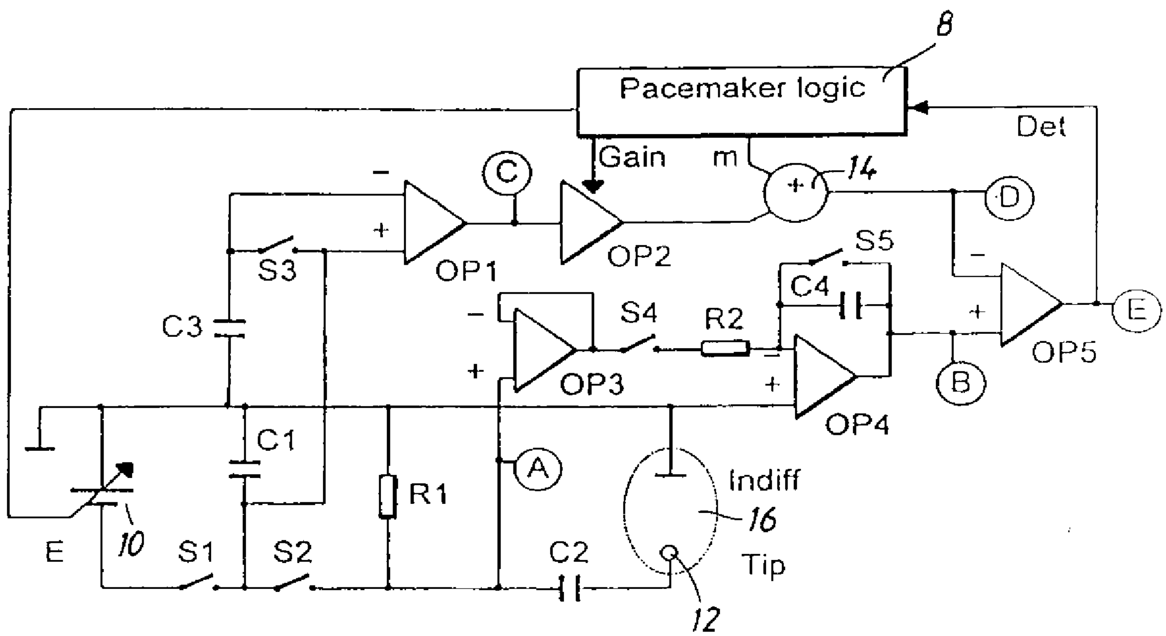

8
Pacemaker logic
Det
Gain
m
14
C
D
OP1
OP2
S3
S5
C4
C3
S4
R2
OP3
OP4
OP5
E
B
C1
A
R1
Indiff
16
E
10
S1
S2
C2
Tip
12

Fig.5

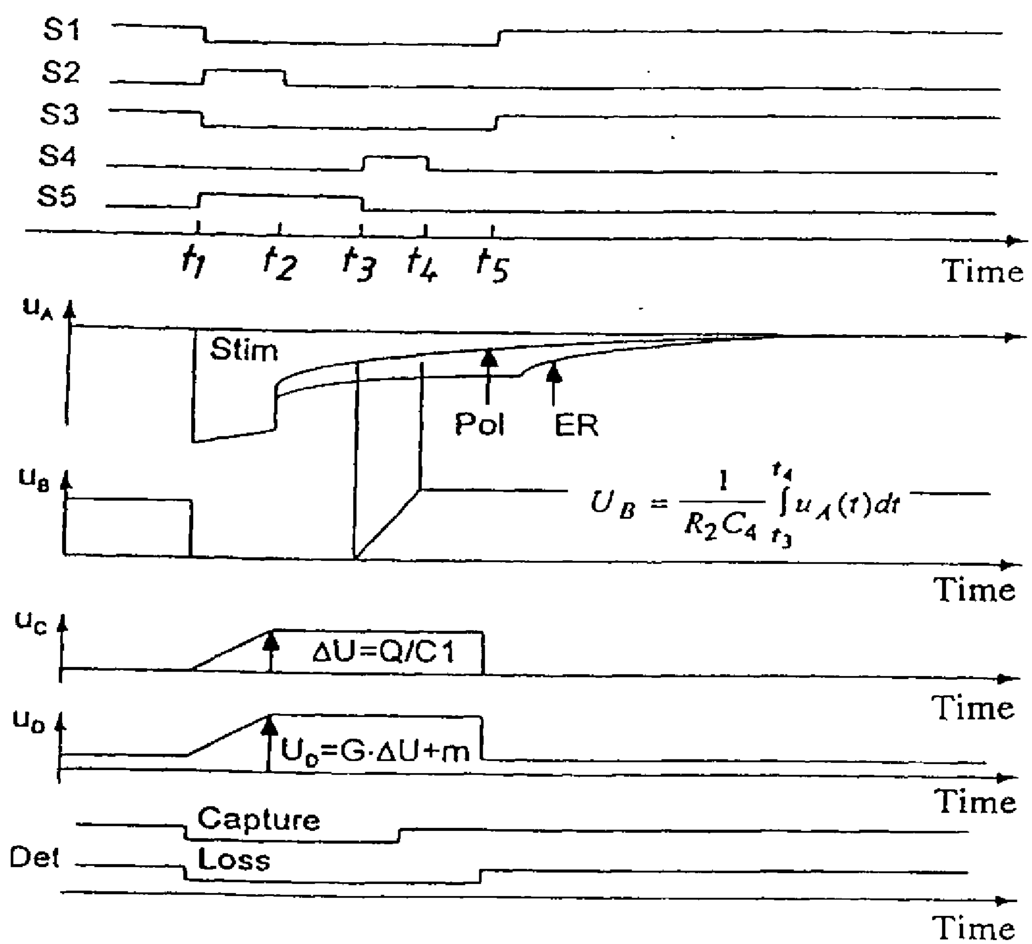
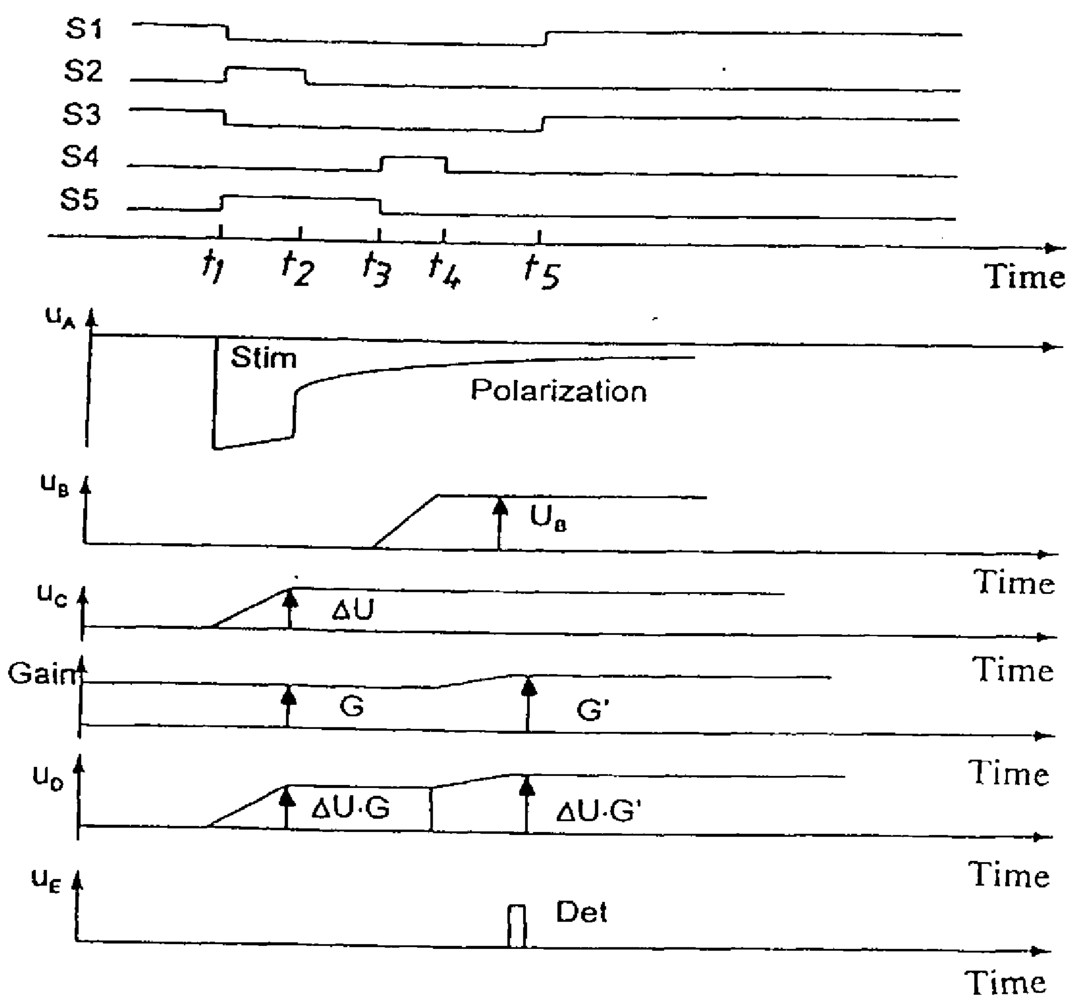

S1
S2
S3
S4
S5
t1
t2
t3
t4
t5
Time
uA
Stim
Pol
ER
uB
$U_B = \frac{1}{R_2 C_4} \int_{t_3}^{t_4} u_A(t)\,dt$
Time
uC
ΔU=Q/C1
Time
uD
UD=G·ΔU+m
Time
Capture
Det
Loss
Time

Fig. 6


S1
S2
S3
S4
S5
t1
t2
t3
t4
t5
Time
U_A
Stim
Polarization
U_B
U_B
Time
U_C
ΔU
Time
Gain
G
G'
Time
U_D
ΔU·G
ΔU·G'
Time
U_E
Det
Time

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EUROPEAN SEARCH REPORT

Application Number
EP 99 10 1110.7
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DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
A	US 5350410 A (J.A. KLEKS ET AL.), 27 September 1994 (27.09.94) * see the whole document * --	1-14	A61N 1/37 A61N 1/365
A	US 5718720 A (D. PRUTCHI ET AL.), 17 February 1998 (17.02.98) * see the whole document * --	1-14	
A	US 5431693 A (E.A. SCHROEPPEL), 11 July 1995 (11.07.95) * see the whole document * --	1-14	
A	US 5766230 A (A.G. ROUTH ET AL.), 16 June 1998 (16.06.98) * see the whole document * -----	1-14	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	7 May 1999	JONI SAYELER

CATEGORY OF CITED DOCUMENTS

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